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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,966	03/31/2005	James Guillet	1047-025	6278
34060	7590	08/13/2009		
MICHAEL N. HAYNES 1341 HUNTERSFIELD CLOSE KESWICK, VA 22947			EXAMINER LIGHTFOOT, ELENA TSOY	
			ART UNIT 1792	PAPER NUMBER
			MAIL DATE 08/13/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,966

Applicant(s)

GUILLET ET AL.

Examiner

Elena Tsoy Lightfoot

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15-17, 67-72, 74-76 and 82-88 is/are pending in the application.
- 4a) Of the above claim(s) 1, 15-17, 67, 68, 70 and 83-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69, 71, 72, 74-76 and 82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Response to Amendment

Amendment filed on June 22, 2009 has been entered. Claims 1, 15-17, 67-72, 74-76, 82-88 are pending in the application.

Claims examined on the merits are 69, 71, 72, 74-76, and 82.

Status of Claims

Claims 1, 15-17, 67-72, 74-76, 82-88 are pending in the application. Claims 1, 15-17, 67-68, 70, 83-88 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention and species.

Abstract

1. Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

2. The Abstract appears to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

For example, "Certain exemplary embodiments can provide a composition comprising water droplets comprising a dispersion of particles comprising a polymer comprising at least one hydrophobic substituent and at least one hydrophilic substituent"; "The polymer can be formed **from** polymerization and/or copolymerization".

Applicant submits that the Abstract of the present Application as originally submitted was less than 150 words in length and thus was "brief", pertained to the "technical disclosure", commenced on a separate sheet under the heading "Abstract", and the sheet on which it appeared did not include other parts of the application or other material. Thus, the PATENT Application 10/529,966 Attorney Docket 1047-025 Abstract of the present Application as originally submitted fully complies with the requirements of 37 C.F.R. 1.72(b). For at least these reasons, Applicant respectfully requests a withdrawal of the objection to the Abstract.

The Examiner respectfully disagrees with this argument. Abstract fails to describe the general nature of composition: Abstract describes a composition that may comprise water *droplets* comprising a dispersion of particles. It is well known in the art that a composition may comprise water *droplets* only if the composition is in the form of **emulsion**. However, the Applicants' specification describes aqueous solution or dispersion of solid particles but no emulsion. The Applicants' specification discloses that the composition may be **applied** as water droplets comprising a dispersion of particles.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Rejection of claim 76 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for solid particles being less than 1000 **nanometers**, does not reasonably provide enablement for up to 1000 **microns** as claimed in 76 has been withdrawn due to amendment.
5. Claims 69, 71, 72, 74-76, and 82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. Claim 69 recites “internally **substantially** crosslinked polymer” which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed “internally crosslinked polymer” (See P3, 42, 44 of Published Applicants’ Application).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 69, 71-72, 74-76, and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 69 recites “internally **substantially** crosslinked polymer” which renders the claim indefinite because the meaning of the phrase is not clear.

Claim 69 recites the limitation “the N-isopropyl acrylamide” in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 72 recites the limitation “the hydrophilic monomer” in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 69, line 1, “an aqueous **solution** comprising a **dispersion** of solid particles”, which renders the claim indefinite because it is not clear what is claimed a “solution” or “dispersion”? For examining purposes the phrase was interpreted as “an aqueous ~~solution comprising a~~ **dispersion** of solid particles” or “an aqueous colloidal solution comprising a ~~dispersion~~ of solid

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nanoparticles” since it is well known in the art that a dispersion of colloidal particles may be called “solution”.

Applicant submits that a person having ordinary skill in the art, when reading the claims in light of the specification, particularly at least paragraphs 0009-0012, would find "an aqueous solution comprising a dispersion" clear. Consequently, reconsideration and withdrawal of these rejections is respectfully requested.

The Examiner respectfully disagrees with this argument. It is well known in the art that an aqueous *solution* of a solid polymer may be formed by *dissolving* a solid water-soluble polymer in water whereas water-insoluble polymer can be only *dispersed* in water because it cannot be dissolved in water, as evidenced by US 5270055 to Moest (See column 2, lines 55-60). (Moest shows that a water-insoluble polymer, such as ethylcellulose, is used as an aqueous **dispersion**, and a water-soluble polymer, such as methylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose or polyvinylpyrrolidone is used as an aqueous **solution**).

It is also well known in the art that blending an aqueous *dispersion* of a water-insoluble polymer with an aqueous *solution* of a water-soluble polymer results in a blended **dispersion**, as evidenced by US 2509857 to Borchardt et al (See column 1, lines 41-47).

Therefore, the limitation of claim 69 “an aqueous **solution** comprising a **dispersion** of solid particles” is a contradictory statement.

Examiner Note

All grounds of rejections discussed in the previous Office Action have been withdrawn due to amendment.

The new grounds of rejections are as follows:

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 69, 71-72, and 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshioka et al (US 5,225,062).

Yoshioka et al discloses an aqueous gel composition comprising a crosslinked temperature-responsive polymeric compound comprising copolymer of *N-isopropylacrylamide* (NIPAM) (See column 3, lines 58, column 6, line 31) with other monomers including any hydrophilic monomers and hydrophobic monomers (See column 3, line 66 to column 4, line 2) such as *methyl methacrylate* (MA) (See column 4, lines 19-21), and having lower critical solution temperature (LCST) that shows, in the presence of water, hydrophobicity (i.e. flocculation or precipitation of the polymer) at a temperature higher than the LCST and changes to show hydrophilicity at a temperature below the LCST, and such a (phase) change is characterized by being thermally reversible (See column 3, lines 11-16). It is preferred to use a temperature-responsive polymeric compound having its LCST at 0°C-90°C (See column 3, lines 33-35). Generally, copolymerization with a hydrophilic monomer will raise the LCST, and copolymerization with a hydrophobic monomer will lower the LCST. With an appropriate selection of the monomers, a copolymer having a desired LCST can be obtained. (See column 4, lines 1-8).

As to heat release, it is well known in the art that temperature-responsive polymeric compounds release heat during their phase change*.

As to claimed range of -3.89 to 4.4°C, note that the Yoshioka et al's range 0°C-90°C overlaps claimed range. It is well settled that overlapping ranges are prima facie evidence of

obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Yoshioka et al's range that corresponds to the claimed range. It is the Examiner's position that NIPAM copolymer an internally crosslinked polymer having phase change within claimed range of -3.89 to 4.4⁰C would have claimed molecular weight and claimed particle size, as required by claims 74-76.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5985573 to Hennink et al is cited here to show that it is well known in the art that copolymers which contain **N-isopropylamide units** possess LCST (lower critical solution temperature) behaviour. This means that the polymer dissolves well in water at relatively low temperature, whereas at a temperature higher than the LCST phase separation occurs. In this light, reference is made to H. Feil et al. *Macromolecules* 26 (1993), 2496-2500. (See column 3, lines 62-67).

* Feil et al ("Effect of Comonomer Hydrophilicity and Ionization on the Lower Critical Solution Temperature of N-Isopropylacrylamide Copolymers", *Macromolecules* 1993, 26, 2496-2500) discloses an aqueous solution comprising a *crosslinked* polymer comprising N-isopropylacrylamide units, butyl methacrylate (hydrophobic monomer) units and X units, with X being hydrophilic, *hydrophobic*, cationic, or anionic comonomers, which polymer demonstrates good solubility in aqueous solutions at low temperatures but *separate* from solution (i.e. phase transition) when the temperature is raised above the lower critical solution temperature (LCST). An important and useful feature of thermosensitive polymers is the possibility of controlling their LCST by various means, in particular by varying the monomer composition. In general,

the incorporation of hydrophobic comonomers leads to a lower LCST and hydrophilic comonomers to a higher LCST. (See Abstract and P1). Feil et al further teaches *heat of phase separation* (See page 2498).

Response to Arguments

Applicant's arguments with respect to claims 69, 71, 72, 74-76, and 82 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy Lightfoot whose telephone number is 571-272-1429. The examiner can normally be reached on Monday-Friday, 9:00AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elena Tsoy Lightfoot, Ph.D.
Primary Examiner
Art Unit 1792

August 12, 2009

/Elena Tsoy Lightfoot/